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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,550

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Patrick Fogarty

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BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

SGAGIAS, MAGDALENE K

ART UNIT

PAPER NUMBER

1632

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,550	Applicant(s) FOGARTY, PATRICK	
	Examiner MAGDALENE K. SGAGIAS	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/24/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,13-15,27,31 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,13-15,27,31 and 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 11, 13-15, 27, 31, 39-44 are pending and under consideration. The amendment has been entered. Claims 1-10, 12, 16-26, 28-38 are canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the phrase "(ii) inserting cells derived therefrom". It is not clear as to what cells and as to how to insert cells and where to insert cells and as to where these cells derived from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 13-15, 27, 31, 39-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (U.S. Patent 6,291,243 B1 (IDS)).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Fogarty et al. teach that the P element vector can be used to insert exogenous or endogenous nucleic acids into the genomes of mammalian cells including rat and murine (col. 5 lines 42-59). Fogarty et al. teach and claim a method of inserting an exogenous nucleic acid into a non-insect target cell genome, including mouse and rat (col. 5 lines 42-59), using a P element derived vector ('243 claim 12). The P element derived vector comprises a pair of P element transposase recognition sites flanking at least two non-insect cell transcriptionally active expression modules each comprising a coding sequence and a promoter ('243 claim 1). The P element vector taught by Fogarty et al. further comprises that said transposase recognition sites are 31 base pair inverted repeats (**as required in the instant claim 31**). Fogarty teaches that the P element vector comprises an inter P feet domain that is at least 50 bp in length, or usually at least 1000 bp in length corresponding to the nucleic acid to be inserted into the host genome (col. 4 lines 1-11). Fogarty teaches in Fig. 2 (casper4) the white gene is separated from the 5' P foot by a distance less than 1000 bp and that is also the case for the 3' P foot. Fig. 2 (casper4) clearly marks in increments of 1000 the relation of the transcriptionally active white gene and the P feet. This teaching by Fogarty anticipates that a single transcriptionally active gene is separated from a P element transposase domain by a distance of about 1000 bp or less (see figure 2) (**as required in the instant claims 11, 27 and 41**). The claims in the Fogarty patent are drawn to a method of using a P element vector that comprises at least two non-insect cell

genes flanked by a pair of P element transposase recognition sites and in the specification teach that a single gene can be flanked by said transposase recognition sites (col. 5 lines 5-9). Fogarty et al. explicitly states that " Vectors of this embodiment that include a single transcriptionally active gene may be prepared and used as described below, where the following description is provided in terms of vectors that include at least two transcriptionally active genes." (col. 5 lines 5-9). Fogarty et al. ('243 claim 14) further teach that a second vector can be delivered using the claimed method **(as required by instant claims 11, 27, 41)**. Fogarty teaches that the claimed method, which is a transformation method, can be used for the creation of transgenic animals, including rodents (col. 1 lines 16-28). Fogarty teaches a P element vector for introducing an exogenous nucleic acid into a target non-insect cell genome, said vector comprising: a pair of P element transposase recognized insertion sequences flanking at least two non-insect cell transcriptionally active expression modules each comprising a coding sequence and a promoter, wherein said vector further comprises transposase domain(see claims 1 and 3, column 13)(as required in the instant claims 11, 27, 41). Fogarty also teaches, the said method further comprises introducing a second vector comprising a transposase domain into said cell (see claim 14 and column 6, lines 2-11)**(as required in the instant claims 11, 27, 41, 13, 14, 43, 44)**. Fogarty for example, this vector could allow the potential for analyzing genes on the size of the human huntington gene (.about.150-200 kb)(see column 11, lines 27-31) **(as required in the instant claim 15)**.

Thus, Fogarty et al anticipates the claimed invention.

Applicants argue that the Examiner points to col. 5, lines 5-10 of the '243 patent for support for the single transcriptionally active gene embodiment, and to col. 4. lines 6-7 for support for the element of the single transcriptionally active gene being "separated from one of said p-element transposase recognized insertion sequences Yet, col. 4, lines 6-7 of the '243

patent refers to the length of the "inter P feet domain," not the distance between one P-element transposase recognized insertion sequence and the single transcriptionally active gene specified in the claims. The "inter P feet domain" is the domain or region of the vector located or positioned between both of the P feet which includes the "at least two transcriptionally active genes and the exogenous nucleic acid" referred to in the '243 patent (see col. 4, lines 1-11 of the '243 patent). This passage does not refer to the distance between one of the P-element transposase recognized insertion sequences and the single transcriptionally active gene, which as presently claimed must be 1,000 bp or less.

These arguments are not persuasive because the Examiner inadvertently pointed to the inappropriate column in order to refer to the distance between one of the P-element transposase recognized insertion sequences and the single transcriptionally active gene. The Examiner corrected this deficiency as cited above by referring to appropriate citation in the '243 patent (see above quotation): "Fogarty teaches that the P element vector comprises an inter P feet domain that is at least 50 bp in length, or usually at least 1000 bp in length corresponding to the nucleic acid to be inserted into the host genome (col. 4 lines 1-11). Fogarty teaches in Fig. 2 (casper4) the white gene is separated from the 5' P foot by a distance less than 1000 bp and that is also the case for the 3' P foot. Fig. 2 (casper4) clearly marks in increments of 1000 the relation of the transcriptionally active white gene and the P feet. This teaching by Fogarty anticipates that a single transcriptionally active gene is separated from a P element transposase domain by a distance of about 1000 bp or less (see figure 2) **(as required in the instant claims 11, 27 and 41).**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13-15, 27, 31, 39-42 rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Art Unit 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632